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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

In re: Effexor XR Antitrust Litigation This document relates to: All Actions	Lead case: 3:11-cv-05479-PGS-LHG

MEMORANDUM OF LAW IN SUPPORT OF PLAINTIFFS' MOTION TO COMPEL ZYDUS PHARMACEUTICALS U.S.A. AND CADILA HEALTHCARE LIMITED TO PRODUCE DOCUMENTS

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I. INTRODUCTION

The instant Motion seeks to compel compliance with a non-party subpoena issued pursuant to Federal Rule of Civil Procedure 45 to Zydus Pharmaceuticals U.S.A. and Cadila Healthcare Limited (together, "Zydus") in *In re Effexor XR Antitrust Litigation*, No. 11-cv-05479 (D.N.J.) (the "*Effexor XR* Action"), which is pending before this Court.[1] The subpoena to Zydus (the "Subpoena") has been outstanding for more than nine months.[2]

Zydus, a generic drug manufacturer, filed an abbreviated new drug application ("ANDA") seeking approval to market a generic version of Effexor XR in late 2007, but did not begin selling generic Effexor XR until June 1, 2011. Plaintiffs allege that Zydus would have been ready, willing, and able to sell its generic version of Effexor XR earlier absent Defendants' conduct challenged in the *Effexor XR* Action. The Subpoena seeks documents relevant to those allegations.

Despite failing to serve timely written objections (or any objections at all), thus waiving all objections to the Subpoena, Zydus has refused to produce the following categories of document relevant to the *Effexor XR* Action: (1) data showing its sales of generic Effexor XR; (2) its complete ANDA file for generic

[1] Zydus is headquartered in Pennington, New Jersey, and so in addition to being the subpoena-issuing court, this Court is the proper venue for enforcement of the Subpoena pursuant to Fed. R. Civ. P. 45(d)(2)(B)(i).

[2] The Subpoena is Exhibit A to the accompanying Declaration of A. Luke Smith ("Smith Decl."). All Exhibits referenced herein are attached to the Smith Decl.

Effexor XR, including internal correspondence and correspondence with the Food and Drug Administration ("FDA"); (3) documents regarding the readiness, willingness and ability of Zydus to launch generic Effexor XR, including documents sufficient to show Zydus's manufacturing capacity; (4) Zydus forecasts/projections containing the anticipated regulatory approval dates, launch dates, and sales (in dollars and units) for Zydus's generic Effexor XR, including such documents generated prior to Zydus agreeing to settle the Wyeth-Zydus Litigation;[3] (5) documents regarding the negotiation and settlement of the Wyeth-Zydus Litigation; and (6) communications with other generic Effexor XR ANDA filers regarding Effexor XR or generic Effexor XR.

Defendants agree that these documents are relevant, as evidenced by the fact that Defendants issued subpoenas to Zydus seeking documents and testimony on nearly identical topics. *See* Ex. E, Defendants' May 28, 2018 subpoenas to Zydus.

II. FACTUAL BACKGROUND

A. The Challenged Conduct

Plaintiffs allege that Wyeth engaged in an anticompetitive scheme to fraudulently obtain patents purportedly covering Effexor XR, wrongfully list them

[3] The "Wyeth-Zydus Litigation" refers to the Effexor XR patent infringement litigation that Wyeth Pharmaceuticals, Inc., Wyeth-Whitehall, and Wyeth Pharmaceuticals Company (collectively, "Wyeth") filed against Zydus.

in the FDA's "Orange Book,"[4] and baselessly assert them against potential generic Effexor XR competitors in sham litigations to trigger automatic 30-month stays of FDA approval. *See In re Lipitor Antitrust Litig. & In re Effexor XR Antitrust Litig.*, 868 F.3d 231, 243 (3d Cir. 2017). Plaintiffs further allege that Wyeth and Teva entered into a "pay-for-delay" agreement under the cover of the baseless Effexor XR patent lawsuit Wyeth filed against Teva. In that agreement, Wyeth paid Teva to delay Teva's generic Effexor XR launch, and Wyeth agreed not to launch an "authorized generic" in competition with Teva for 6 months. *Id.*

Plaintiffs allege that, by fraudulently obtaining these patents, wrongfully listing them in the Orange Book, filing serial sham litigations, and entering into settlement agreements with seventeen potential generic competitors (including Zydus) before any decision on the merits of those cases, Wyeth successfully blocked generics from coming to market for two years, from June 2008 until July 1, 2010 (the date that Teva was permitted to launch its generic Effexor under the Wyeth-Teva settlement). *In re Effexor XR Antitrust Litig.*, 2014 U.S. Dist. LEXIS 142206, at *36-41 (D.N.J. Oct. 6, 2014). Plaintiffs allege that, were it not for this unlawful scheme, Teva would have obtained approval for and launched its generic Effexor

[4] The "Orange Book" is an FDA publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations" that contains, among other things, the patents associated with brand name drugs for which generic manufacturers are seeking FDA approval to market.

XR in June 2008; Wyeth would have simultaneously launched an authorized generic version of Effexor XR (itself or through an agreement with a third party); and subsequent generic Effexor XR ANDA filers (like Zydus) would have obtained approval for and launched their generics earlier than they actually did, resulting in substantially lower brand and generic Effexor XR prices.

Plaintiffs allege injury in the nature of overcharge damages, which are generally measured by the quantities of brand and generic Effexor XR the Plaintiffs and their respective class members bought, multiplied by the difference between (i) the net prices the Plaintiffs and their respective class members paid for brand and generic Effexor XR (including from Zydus) and (ii) the net prices Plaintiffs would have paid had generic Effexor XR competition not been delayed by Wyeth's and Teva's anticompetitive conduct.

B. Plaintiffs Subpoena Zydus

Realizing that Zydus possesses certain information that is not available from Wyeth or another party, Plaintiffs served the Subpoena on May 18, 2018. *See* Ex. A, Subpoena. It requests, *inter alia*, (i) transaction-level sales data showing Zydus's sales of generic Effexor XR (Requests 13-18); (ii) Zydus's Effexor XR ANDA file, including the ANDA itself, all amendments and supplements thereto, all communications to and from the FDA, and Zydus's internal communications about its Effexor XR ANDA (Requests 6-7); (iii) Zydus's forecasts and launch plans for

its generic version of Effexor XR and related documents (Request 4); (iv) documents concerning Zydus's manufacturing capacity and its preparations to launch its generic Effexor XR product (Request 8); (v) draft and final agreements pertaining to generic Effexor XR (Request 12) and communications concerning negotiation of the same (Request 3); and (vi) Zydus's communications with other Effexor XR ANDA filers (Requests 10 & 11). In addition, with the Subpoena, Zydus was served a copy of the Protective Order entered by the Court in this matter.

Zydus never served any written responses or objections to the Subpoena. Smith Decl. ¶ 3. On June 14, 2018, counsel for Plaintiffs called Zydus's corporate offices to inquire about the status of the Subpoena, and Zydus's counsel called back the following day. Smith Decl. ¶¶ 4-5.

Following this initial call, Plaintiffs emailed Zydus's counsel on June 22, 2018 summarizing the categories of requested documents. Ex. C at 15-17. Thereafter, Plaintiffs' counsel made a good faith effort to meet and confer with Zydus's counsel to reach an agreement regarding Zydus's compliance with the Subpoena, but Zydus's counsel failed to respond to Plaintiffs for long periods of time. Smith Decl. ¶ 7; Ex. C at 7-9. Plaintiffs' counsel eventually reached Zydus's counsel by phone on September 11, 2018, and reiterated Plaintiffs' request for the documents at issue in this motion. Zydus's counsel stated he would confer again with Zydus and reply the following week. Smith Decl. ¶ 8.

On or about September 21, 2018, having not heard back from Zydus's counsel, Plaintiffs' counsel again emailed Zydus's counsel regarding Zydus's failure to produce the requested documents. Smith Decl. ¶ 9. On or about October 12, 2018, Zydus produced an incomplete set of marketing, launch planning, and sales forecasting documents generated during the period after Zydus had reached a settlement in principle of the Wyeth-Zydus Litigation, and failed to produce *any* material from the other categories of documents sought by this motion, namely: (1) Zydus's sales data; (2) Zydus's ANDA file; (3) documents sufficient to show Zydus's capacity and ability to manufacture generic Effexor XR; (4) Zydus's *pre*-settlement forecasts and launch plans for its generic version of Effexor XR and related documents;[5] (5) documents relating to the negotiation and settlement of the Wyeth-Zydus Litigation; and (6) documents relating to Zydus's communications with other Effexor XR ANDA filers. Smith Decl. ¶¶ 10-11.

Zydus has failed to produce these six categories of relevant documents despite a lengthy meet and confer and despite Zydus's failure to object to the Subpoena, thus waiving all objections to the Subpoena, and even though it would not be burdensome

[5] Zydus has not yet claimed that it has produced all responsive forecasts and launch planning documents. Based on our review of documents produced by other Effexor XR ANDA filers, Plaintiffs expect that Zydus prepared forecasts and launch date projections prior to agreeing to settle the Zydus-Wyeth Litigation, and Zydus has not denied the existence of such pre-settlement documents. However, Zydus has not produced *any* such forecasting and launch planning documents created before Zydus agreed to settle with Wyeth.

for Zydus to produce these documents. Zydus should be compelled to produce these documents without further delay.

III. ZYDUS SHOULD BE COMPELLED TO PRODUCE THE REQUESTED DOCUMENTS

Zydus has never served any written objections, let alone timely ones, and thus has waived all objections to the Subpoena. Regardless, the requested documents are relevant to Plaintiffs' claims in this action, not obtainable from Defendants, and not burdensome to produce. Plaintiffs' motion to compel should therefore be granted.

A. Legal Standard

Rule 26(b)(1) provides that discovery encompasses that which "is relevant to any party's claim or defense and proportional to the needs of the case," and "need not be admissible in evidence to be discoverable." Fed. R. Civ. P.26(b)(1). Relevancy is broadly construed for discovery purposes and is not limited to the precise issues set out in the pleadings or the merits of the case. *See Oppenheimer Fund, Inc. v. Sanders*, 437 U.S. 340, 351 (1978) ("The key phrase in this definition—'relevant to the subject matter involved in the pending action'—has been construed broadly to encompass any matter that bears on, or that reasonably could lead to other matters that could bear on, any issue that is or may be in the case.").

"The party resisting production of discovery bears the burden of establishing lack of relevancy or undue burden." *EEOC v. Princeton Healthcare Sys.*, 2012 U.S. Dist. LEXIS 65115, at *54-55 (D.N.J. May 9, 2012). As this court has stated on

numerous occasions, the burden of demonstrating "the unreasonableness or oppressiveness" of a subpoena is a "heavy" one. *See, e.g.*, *Halpin v. Barnegat Bay Dredging Co.*, 2011 U.S. Dist. LEXIS 68828, at *35 (D.N.J. June 27, 2011); *Malibu Media, LLC v. Does*, 2012 U.S. Dist. LEXIS 175919, at *6 (D.N.J. Dec. 12, 2012); *Dexter v. Cosan Chem. Corp.*, 2000 U.S. Dist. LEXIS 22134, at *7-8 (D.N.J. Oct. 24, 2000). To overcome the presumption in favor of discovery, a respondent must "demonstrate to the Court that the requested documents either do not come within the broad scope of relevance as defined in Fed. R. Civ. P. 26(b)(1) or else that they are of such marginal relevance that the potential harm occasioned by discovery would outweigh the ordinary presumption in favor of broad disclosure." *EEOC v. Princeton Healthcare Sys.*, 2012 U.S. Dist. LEXIS 65115, at *54 (D.N.J. May 9, 2012). Moreover, "[t]he objecting party must specifically show how each discovery request is objectionable." *Love v. N.J. Dep't of Corr.*, 2017 U.S. Dist. LEXIS 128905, at *7 (D.N.J. Aug. 11, 2017) (citation omitted). "Objections must state with specificity the objection and how it relates to the particular request being opposed, and not merely that it is 'overly broad and burdensome' or 'oppressive' or 'vexatious' or 'not reasonably calculated to lead to the discovery of admissible evidence.'" *Id.* (citations omitted).

B. Zydus Waived All Objections to the Subpoena by Failing to Timely Serve Written Objections.

Zydus has waived all objections to the Subpoena by failing to serve written

objections *at all*, much less timely written objections. The Subpoena was served on May 18, 2018. *See* Ex. B. Any written objections to non-party subpoenas must be served no later than 14 days after the subpoena was served. Fed. R. Civ. P. 45(d)(2)(B). Zydus failed to timely serve objections within 14 days of being served with the subpoena, or thereafter. Smith Decl. ¶ 3.[6]

Zydus's failure to timely serve written objections constitutes waiver of all rights to assert those objections. *See, e.g.*, *La. Generating, L.L.C. v. Ill. Union Ins. Co.*, 2011 U.S. Dist. LEXIS 143679, at *6 (M.D. La. Dec. 14, 2011) ("failure to serve timely objections to a Rule 45 subpoena generally results in a waiver of all grounds for objection, including privilege."); *In re Corso*, 328 B.R. 375, 384 (E.D.N.Y. 2005) ("The fourteen day time limitation to serve written objections to a subpoena is crucial as failure to do so typically constitutes a waiver of such objections"); *Packer v. Hansen*, 1999 U.S. Dist. LEXIS 17618, at *7 (E.D. Pa. Nov. 12, 1999) ("this Court must find that [the nonparty subpoena recipient's] right to object was waived because no objections were ever filed.").

C. Zydus's Generic Effexor XR Sales Data Is Relevant, Not Obtainable from Defendants, and Not Burdensome to Produce

Even putting aside Zydus's waiver of any objections to the Subpoena, the requested sales data is relevant and not burdensome to produce, and should be

[6] Again, Plaintiffs' counsel's first communication with Zydus counsel was June 15, 2018, nearly a month after the subpoena was served. Smith Decl. ¶¶ 4-5.

promptly produced.

Requests 13-15 of the Subpoena seek Zydus's transactional sales data showing its sales of generic Effexor XR and related documentation that is needed to understand any fields and codes that are commonly included in such transactional sales data. This information is relevant to Plaintiffs' allegation that Wyeth's and Teva's anticompetitive conduct harmed Plaintiffs by causing them to pay higher prices than they otherwise would have. Plaintiffs must demonstrate antitrust impact (injury, in the form of higher prices, caused by the anticompetitive conduct) and class-wide damages (the difference between the brand and generic prices actually paid by Plaintiffs and the classes and the prices that would have been paid if generic Effexor XR had been available earlier). In order to calculate the net prices purchasers paid for generic Effexor XR, Plaintiffs need the prices paid by purchasers from Zydus (and other generic Effexor XR sellers). Zydus's sales data supplies inputs used to determine the amount of generic Effexor XR purchased, and the net prices actually paid for the generic. These inputs will be used by Plaintiffs and their experts to model the quantities that would have been purchased, and the (lower) prices Plaintiffs would have paid for brand and generic Effexor XR absent the anticompetitive conduct. Damages are the difference between what the Plaintiffs actually spent (the volumes purchased multiplied by the net prices paid) and what they would have spent absent the anticompetitive conduct (the modeled figures).

See, e.g., *In re Wellbutrin XL Antitrust Litig.*, 2011 WL 3563385, at *14-15 (E.D. Pa. Aug. 11, 2011) (discussing "before and after" methodology, which "produces an aggregate damages estimate that is based on deriving a benchmark for generic prices in the 'but for world' based on the actual experience for branded and generic prices after entry"); *Meijer, Inc. v. Warner Chilcott Holdings Co. III*, 246 F.R.D. 293, 311-12 (D.D.C. 2007) (noting actual generic prices are used for damages calculation in delayed generic entry antitrust cases).

The transactional sales data sought by Requests 13-15 of the Subpoena is routinely requested and produced by non-parties—in this case and others—under similar circumstances, usually voluntarily but by court order if needed. *See, e.g.*, *Direct Purchaser Class v. Apotex Corp.*, 2017 U.S. Dist. LEXIS 159585, at *3-4 (S.D. Fla. May 15, 2017) (enforcing non-party subpoena in antitrust case involving delayed generic entry that sought "sales data for generic Celebrex and/or authorized generic Celebrex in electronic format, at the transaction level" because such data would allow plaintiffs' economic experts to determine price for generic Celebrex absent defendant's anticompetitive conduct); *In re Namenda Direct Purchaser Antitrust Litig.*, 2017 U.S. Dist. LEXIS 173403, at *7-10 (S.D.N.Y. Oct. 19, 2017) (ordering non-party generic to produce transactional sales data in an antitrust case because monthly sales summaries were inadequate). "[T]he production of voluminous transactional data . . . in an antitrust case is routine and happens in every

case." F. Matthew Ralph & Caroline B. Sweeney, *E-Discovery and Antitrust Litigation*, 26 ANTITRUST 58, 61 (2011) (quotation and citation omitted). Antitrust cases require substantial data analysis. *See Mitsubishi Motors Corp. v. Soler Chrysler-Plymouth, Inc.*, 473 U.S. 614, 632 (1985) ("antitrust issues, prone to complication, require sophisticated legal and economic analysis"). Denying relevant data discovery can constitute reversible error. *See, e.g.*, *Valley Drug Co. v. Geneva Pharm., Inc.*, 350 F.3d 1181, 1192 (11th Cir. 2003) (district court erred by prohibiting certain data discovery).

Indeed, Zydus produced the very same sales data sought by this motion in *In re Niaspan Antitrust Litig.*, Case No. 13-md-2460 (E.D. Pa.), where it was also a non-party, after the plaintiffs in that case filed a motion to compel. Smith Decl. ¶ 17 & Ex. D. The same result should obtain here. Plaintiffs are simply requesting that Zydus produce the generic Effexor XR sales data it possesses in the form in which it is kept in the ordinary course of Zydus's business. Plaintiffs aren't requesting that Zydus create any sales data that it doesn't already possess. Indeed, Zydus clearly possesses this data since it produced similar data in the *Niaspan* litigation. In addition, Zydus has articulated no burden associated with producing this data, nor can Zydus show any burden likely to outweigh the benefit of the requested discovery to this case, given that the data is highly relevant to damages and antitrust injury. *See, e.g.*, *Mallinckrodt LLC v. Actavis Labs.*, 2017 U.S. Dist. LEXIS 18909, at *10

(D.N.J. Feb. 10, 2017) (compelling production where respondent "failed to demonstrate that the discovery sought [was] disproportionate to the needs of the case or constitute[d] an undue burden"); *Biotechnology Value Fund, L.P. v. Celera Corp.*, 2014 U.S. Dist. LEXIS 119878, at *8-9 (D.N.J. Aug. 27, 2014) (same).

D. Zydus's Generic Effexor Regulatory Files Are Relevant, Not Obtainable From Defendants, and Not Burdensome to Produce

Zydus should also be compelled to promptly produce its generic Effexor XR ANDA file—including all ANDA filings and related correspondence, internally and with the FDA, as sought in Requests 6 and 7—because these documents are relevant and not burdensome to produce, and because Zydus has waived any objection to Plaintiffs' request for Zydus's ANDA file.

Zydus's ANDA file for generic Effexor XR is relevant to Plaintiffs' allegation that absent Wyeth's and Teva's anticompetitive conduct, Zydus would have launched its generic version of Effexor XR sooner, resulting in purchasers paying lower prices earlier than they actually did. Indeed, Zydus's ANDA file contains critical information regarding any regulatory issues Zydus experienced in seeking FDA approval of its generic Effexor XR ANDA and the steps and time Zydus took to resolve those issues. Zydus's internal communications regarding the status and priority assigned to prosecuting its ANDA are relevant to understanding the efforts and amount of time Zydus expended to resolve regulatory issues involving its ANDA as well as the motives and incentives affecting Zydus, and the extent to which

the challenged settlement agreement between Wyeth and Teva affected those motives and incentives. Such information is relevant to establishing the date on which Zydus would have launched generic Effexor XR absent the challenged conduct. Zydus's ANDA file is thus relevant to Plaintiffs' calculation of damages.

Plaintiffs and Defendants do not possess Zydus's ANDA file, so these relevant documents must be obtained from Zydus. And, once again, Zydus has not articulated any burden associated with production of these documents, nor can it, given that the ANDA file includes a discrete set of easily-identifiable documents within Zydus's possession. *See Mallinckrodt*, 2017 U.S. Dist. LEXIS 18909, at *10; *Biotechnology Value Fund*, 2014 U.S. Dist. LEXIS, at *8-9.

E. Zydus's Manufacturing Documents Are Relevant, Not Obtainable From Defendants, and Not Burdensome to Produce

Zydus should also be compelled to promptly produce its generic Effexor XR manufacturing documents because they are relevant and not burdensome to produce, and because Zydus has waived any objection to Plaintiffs' requests.

Documents sufficient to show Zydus's manufacturing capacity as set forth in Request 8 of the Subpoena are relevant to the steps and time it took Zydus complete those steps and show when, from a manufacturing perspective, Zydus would have been able to launch generic Effexor XR absent the challenged conduct.

The parties do not possess Zydus's manufacturing documents, so they must be obtained from Zydus. Zydus has not articulated any burden associated with

production of these documents, nor can it, given that these manufacturing capacity planning documents are a limited set of documents within Zydus's possession. *See Mallinckrodt*, 2017 U.S. Dist. LEXIS 18909, at *10; *Biotechnology Value Fund*, 2014 U.S. Dist. LEXIS, at *8-9.

F. Zydus's Forecasting and Projection Documents are Relevant, Not Obtainable from Defendants, and Not Burdensome to Produce

Request 4 of the Subpoena seeks "draft and final forecasts/projections containing the anticipated regulatory approval dates, launch dates, sales (in dollars and units), including assumptions used, for Generic Effexor XR, and/or any Authorized Generic Effexor ER." Ex. A (Subpoena), at 16. Zydus should also be compelled to promptly produce its generic Effexor XR forecasting and projection documents, including all such documents created before Zydus and Wyeth settled the Wyeth-Zydus Litigation, because they are relevant and not burdensome to produce, and because Zydus has waived any objection to Plaintiffs' requests for these documents.

Zydus's forecasts and launch plans for its generic version of Effexor XR and related documents are relevant to Plaintiffs' claims, as they reflect a knowledgeable market participant's contemporaneous expectations of the timing and impact of generic entry on (a) brand and generic market share, and (b) market prices. In addition, Zydus's pre-settlement forecasts and launch plans are probative of when Zydus believed generic competition would have begun absent the challenged delay

in generic competition, and what the effect of that earlier competition would have been on brand and generic Effexor XR units and prices. Plaintiffs' experts are permitted to and often do use the forecasts of knowledgeable market participants like Zydus to determine what the price of a generic drug would have been as a function of the number of generic firms expected to enter the market, and what generic market share would have been based on the timing of forecasted generic entry. *See, e.g.*, *In re Solodyn (Minocycline Hydrochloride) Antitrust Litig.*, 2017 WL 4621777, at *7-9 (D. Mass. Oct. 16, 2017) (certifying a class of direct purchasers where the plaintiffs' expert (a) relied on nonparty and party generic company forecasts as common evidence of classwide impact, and (b) used these generic company forecasts to calculate what the generic market share would have been, and damages); *In re Lidoderm Antitrust Litig.*, 2017 WL 679367, at *9-10 (N.D. Cal. Feb. 21, 2017) (certifying the direct purchaser class in a similar case challenging a "no-authorized generic" promise where the plaintiffs' expert relied on generic company forecasts as one form of evidence of classwide impact); *Wellbutrin XL*, 2011 WL 3563385, at *12 (class certification granted where plaintiffs' evidence of classwide injury included nonparty generic company forecasts); *In re Neurontin Antitrust Litig.*, 2011 WL 286118, at *7-8 (D.N.J. Jan. 25, 2011) (same); *Teva Pharms. USA, Inc. v. Abbott Labs.*, 252 F.R.D. 213, 229 (D. Del. 2008) (same). Manufacturers' sales forecasts (like those requested from Zydus) also typically reflect the expectation that all

generic sales would be taken from the corresponding brand (here, branded Effexor XR), not from other, non-bioequivalent products, which is probative of the composition of the relevant antitrust market.

Zydus has failed to produce the requested documents. Although Zydus has produced *some* forecasting documents, all of the forecasting documents Zydus has produced were created *after* Zydus reached an agreement in principle to settle with Wyeth, and thus do not reflect Zydus's *pre*-settlement expectations of the timing and impact of generic entry on brand market share and market prices. Zydus should be compelled to produce the remainder of its forecasting and launch plan documents, including all such documents that were created by Zydus *before* Zydus reached an agreement in principle to settle the Wyeth-Zydus Litigation.[7]

Defendants do not possess Zydus's forecasts or launch plans, so these relevant documents must be obtained from Zydus. And again, Zydus has not articulated any burden objection, nor can it. *See J&C Nationwide*, U.S. Dist. LEXIS 50275, at *7; *In re Seroquel Prods. Liab. Litig.*, 244 F.R.D. 650, 654 (M.D. Fla. 2007). Zydus should thus be compelled to produce these documents; their relevance far outweighs any burden to Zydus, and Zydus has waived any burden or relevance objection anyway by failing to object to the Subpoena.

[7] Again, Zydus has not denied possessing such responsive, relevant forecasting documents that were created before Zydus reached an agreement with Wyeth to settle the Wyeth-Zydus Litigation.

G. Zydus's Documents Relating to the Negotiation and Settlement of the Wyeth-Zydus Litigation Are Relevant, Not Obtainable From Defendants, and Not Burdensome to Produce

Zydus should also be compelled to promptly produce documents relating to the negotiation and settlement of the Wyeth-Zydus Litigation, including all draft and final agreements pertaining to generic Effexor XR and communications concerning negotiation of the same, as well as correspondence with other generic manufacturers regarding the same. These documents—sought by Requests 3 and 12—are relevant and not burdensome to produce, and Zydus has waived any objection to Plaintiffs' requests for these documents.

Zydus's documents relating to the negotiation and settlement of the Wyeth-Zydus Litigation are relevant evidence of when, absent the Defendants' challenged conduct, Zydus would have started selling generic Effexor XR, including e.g., by way of reaching a different agreement with Wyeth providing for an earlier agreed-upon entry date for Zydus's generic Effexor XR product, a patent litigation victory, or a so-called at-risk launch. The date on which Zydus would have launched its generic absent the Defendants' unlawful conduct is relevant to, *e.g.*, economic modeling of the competitive market conditions that would have occurred absent Defendants' challenged conduct.

Zydus should thus be compelled to produce these documents because their relevance far outweighs any burden to Zydus, and because Zydus waived any

relevance or burden arguments anyway by failing to object to the Subpoena.

H. Zydus's Documents Regarding Its Communications With Other Effexor XR ANDA Filers Are Relevant, Not Obtainable From Defendants, and Not Burdensome to Produce

Documents relating to Zydus's communications with other Effexor XR ANDA filers are sought by Subpoena Requests 10 and 11, and are relevant evidence of Zydus's decision to agree to an entry date that was the same as ten other Effexor XR ANDA filers and could explain why Wyeth was concerned with the at-risk launch of other Effexor ANDA filers, which would trigger Teva entering earlier than its agreed upon date with Wyeth. These documents are relevant to the question of when Zydus would have launched its generic absent the Defendants' challenged conduct, which is relevant to *e.g.*, economic modeling of the competitive market conditions that would have occurred absent Defendants' challenged conduct, and damages.

Zydus should thus be compelled to produce these documents, which cannot be obtained from any party to the case, because their relevance far outweighs any burden to Zydus, and because Zydus waived any relevance or burden arguments by failing to object to the Subpoena.

IV. CONCLUSION

For the foregoing reasons, this Court should compel Zydus to promptly produce: (1) Zydus's data showing its sales of generic Effexor XR as set forth in

Requests 13-15; (2) Zydus's ANDA file, including the ANDA itself and all related correspondence internally and with the FDA as set forth in Requests 6-7; (3) documents sufficient to show Zydus's generic Effexor XR manufacturing capacity as set forth in Request 8; (4) Zydus's forecasting and projection documents as set forth in Request 4; (5) documents relating to the settlement negotiation and eventual settlement of the Wyeth-Zydus Litigation as set forth in Requests 3, 11, and 12; and (6) communications with other Effexor XR ANDA filers regarding Effexor XR or generic Effexor XR as set forth in Requests 10 and 11.

Dated: March 27, 2019

Respectfully submitted,

By: */s/ Matthew F. Gately*

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